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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,352	05/12/2006	David Bryant Batt	CNOVA.00004	6398

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EXAMINER	
RAO, DEEPAK R	

ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,352	BATT ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 5-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment filed on December 9, 2009.

Claims 1-2 and 5-32 are pending in this application.

Withdrawn Rejections/Objections:

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

The following rejections are maintained:

1. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As indicated in the previous office action, the metes and bounds of the terms "phenyl radical" and "heteroaryl radical" are not clear.

Applicant relies on the amendment to overcome the rejection, however, claim 32 has neither been amended, nor the claim depends from claim 1 which contains the amended terms.

2. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Zimmermann, U.S. Patent No. 5,521,184. The reasons from the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'reference disclosed compounds are not within the scope of

claim 1 as amended'. However, claim 32 is an independent claim and has not been amended. As previously indicated, the reference discloses a generic group of compounds, a process to prepare the compounds and specific examples falling within the genus. Accordingly, the instantly claimed process is taught in the reference.

3. Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Buerger et al., WO 2002/022597. The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'reference disclosed compounds are not within the scope of claim 1 as amended'. However, claim 32 is an independent claim and has not been amended. As previously indicated, the reference discloses a generic group of compounds, a process to prepare the compounds and specific examples falling within the genus. Accordingly, the instantly claimed process is taught in the reference.

4. Claims 1-2 and 5-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buerger et al., WO 2002/22597. The reasons from the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the compounds exemplified by Buerger only include compounds in which the pyrimidine is substituted by an unsubstituted pyridine and the instant claims specifically recite 6-substituted-3-pyridyl'. This is not found to be persuasive because as

indicated in the previous office action, the reference teaches a generic group of pyrimidine-2-amine compounds, which embraces applicant's instantly claimed compounds. See formula (I) in page 1 wherein R_1 is pyrazinyl, unsubstituted or lower alkyl-substituted pyridyl, etc.; one of R_4-R_8 is a group of formula (II) wherein R_{10} is a phenyl substituted with substituents listed in page 2 which include halogen, haloalkyl, etc. The reference teaches a process to prepare the compounds, see page 18. The reference teaches that the compounds are useful as kinase inhibitors in the treatment of tumors, see page 7.

Further, the reference discloses several compounds falling within the above genus, see for example, the species of the Examples 1-3 and 11-16. Applicant argues that 'Buerger only teaches unsubstituted pyridines and therefore, cannot be said to teach towards specific substitution pattern required for the compounds of the present invention as defined by the revised claim 1'. The specifically disclosed compounds of the reference have an unsubstituted pyridyl attached to the pyrimidine. However, the reference teaches the equivalency of unsubstituted pyridyl and pyridyl substituted with lower alkyl. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art need to make a single change such as replacing the unsubstituted 3-pyridyl with an alternative equivalent group of substituted 3-pyridyl, to arrive at the instantly claimed compound. For all the above reasons, the rejection under 35 U.S.C. 103 is hereby maintained.

5. Claims 1-2, 5-19, and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stein-Gerlach et al., WO 2002/93164. The reasons from the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'even the broad generic disclosure of Gerlach et al. in formula I is to compounds in which the pyridyl moiety attached to the pyrimidine is unsubstituted'. As indicated in the previous office action, the reference teaches a generic group of pyrimidine-2-amine compounds, which embraces applicant's instantly claimed compounds. See formula (I) in page 3 wherein Z can be –NH-CO-X wherein X is a group  , wherein Y, Y' and Y" are as defined in page 4 which include, for example, haloalkyl, etc. Further, the reference teaches several compounds within the genus of formula (I), see for example, the species listed in page 6, particularly, compounds 4-6, 8, 10-12, 18-19, 21-22, etc. The reference teaches that the compounds are useful as pharmaceutical therapeutic agents, see pages 11-22.

Applicant argues that 'the art is clearly teaching that the pyridine moiety should be unsubstituted and is therefore, teaching away from the invention as defined by revised claim 1'. The reference disclosed compounds have an unsubstituted pyridine attached to the pyrimidine ring. However, contrary to applicant's arguments, one of ordinary skill in the art needs to modify a reference disclosed compound by a single modification – such as for example, substituting methyl on the pyridine ring (or replacing the H with CH_3 as the substituent on pyridine ring) to arrive at the instantly claimed compounds. Accordingly, it is maintained that there is sufficient teaching in the copending application that provides motivation to one of

ordinary skill in the art to modify the prior art compounds to prepare the instantly claimed compounds with the reasonable expectation of obtaining compounds having similar properties.

6. Claims 1-2, 5-12, 18-19, and 26-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over pending claims 1-9 of U.S. Patent No. 7,655,669 (issued from application S. No. 10/528,913). The reasons provided in the previous office action are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'claim 1 of the reference defines compounds in which the pyridine moiety is unsubstituted and in contrast, the claims in the present application recite a 6-substituted-3-pyriyl radical'. Contrary to applicant's arguments, one of ordinary skill in the art, in possession of the reference claimed compounds, needs to make a single structural modification – such as for example, substituting methyl on the pyridine ring (or replacing the H with CH_3 as the substituent on pyridine ring) to arrive at the instantly claimed compounds. Accordingly, it is maintained that there is sufficient teaching in the copending application that provides motivation to one of ordinary skill in the art to modify the prior art compounds to prepare the instantly claimed compounds with the reasonable expectation of obtaining compounds having similar properties.

The following rejections are necessitated by the amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-25 and 27-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Claim 7 recites the limitation: $(R_4)_n$ as the substituent on the phenyl ring in structural formula II, wherein n is 0, 1, or 2. There is insufficient antecedent basis for this limitation in claim 1 on which claim 7 is dependent. In claim 1, the formula (I) has a substituent R_2 at the analogous position which is defined to be "a phenyl radical that is substituted at least in the 3-position". However, the dependent claim 7 has a formula wherein the phenyl may not have any substituent, for example, when n is 0. This is inconsistent with the base claim on which claim 7 is dependent. Further, the scope of R_4 goes beyond the substituents intended at the 3-position of the phenyl ring in claim 1 and the claim does not clearly set forth the distinction in type of substituents intended for phenyl ring.
2. Claim 7 is drawn to compound of formula (II) wherein the ring containing A_1, A_2 and A_3 represents a phenyl ring (i.e., A_1, A_2 and A_3 are CH), the ring contains a substituent R_3 which is defined to be $-NR_5R_6$, halogen, $-O-R_8$, etc. There is insufficient antecedent basis for this limitation in claim 1 on which claim 7 is dependent. Claim 1, which is drawn to compound of formula (I) recites a "lower alkoxy-substituted phenyl" at the analogous position. The dependent claim 7 has substituent R_3 on the phenyl ring which is defined to represent a variety of substituents and is therefore, broader than the base claim.

3. Claim 8 recites the limitation "compound of claim 7 wherein R_4 is in at least the 3-position and is represented by halogen, mono- or di-lower alkyl substituted amino; lower alkyl; halo-lower alkyl; lower alkoxy; halo-lower alkoxy; lower alkylthio; or halo-lower alkylthio". There is insufficient antecedent basis for this in claim 1 on which claim 8 is dependent via claim 7. The substituent R_4 is a substituent on the phenyl ring and according to claim 1, this phenyl ring "is substituted in at least the 3-position by fluorine, halo-lower alkyl, halo-lower alkoxy, or halo-lower alkythio". The dependent claim 8 recites more substituents or broader substituent groups than recited in the base claim.
4. Claim 9 recites the limitation: $(R_4)_n$ as the substituent on the phenyl ring in structural formula (III), wherein n is 0, 1, or 2. There is insufficient antecedent basis for this limitation in claim 1 on which claim 9 is dependent. In claim 1, the formula (I) has a substituent R_2 at the analogous position which is defined to be "a phenyl radical that is substituted at least in the 3-position". However, the dependent claim 9 has a formula wherein the phenyl may not have any substituent, for example, when n is 0. This is inconsistent with the base claim on which claim 9 is dependent. Further, the scope of R_4 goes beyond the substituents intended at the 3-position of the phenyl ring in claim 1 and the claim does not clearly set forth the distinction in type of substituents intended for phenyl ring.
5. Claim 10 recites the limitation "compound of claim 9 wherein R_4 is halogen, mono- or di-lower alkyl substituted amino; lower alkyl; halo-lower alkyl; lower alkoxy; halo-lower alkoxy; lower alkylthio; or halo-lower alkylthio". There is insufficient antecedent basis for this in claim 1 on which claim 10 is dependent via claim 9. The substituent R_4 is a

substituent on the phenyl ring and according to claim 1, this phenyl ring "is substituted in at least the 3-position by fluorine, halo-lower alkyl, halo-lower alkoxy, or halo-lower alkythio". The dependent claim 10 recites more substituents or broader substituent groups than recited in the base claim.

6. Claim 14 recites the limitation "wherein the heteroaromatic or heterocyclic radical is selected from ... and 6-substituted-3-pyridyl" in lines 1-3. There is insufficient antecedent basis for this limitation in claim 13 on which claim 14 is dependent. In claim 13, the heteroaromatic radical is the group formed by R^7 and R^8 together and the recitation "6-substituted-3-pyridyl" appears to be out of context.

7. Claim 20 recites the limitation: $(R_4)_n$ as the substituent on the phenyl ring in structural formula (IV), wherein n is 0, 1, or 2. There is insufficient antecedent basis for this limitation in claim 1 on which claim 20 is dependent (via claim 7). In claim 1, the formula (I) has a substituent R_2 at the analogous position which is defined to be "a phenyl radical that is substituted at least in the 3-position". However, the dependent claim 20 has a formula wherein the phenyl may not have any substituent, for example, when n is 0. This is inconsistent with the base claim on which claim 20 is dependent. Further, the scope of R_4 goes beyond the substituents intended at the 3-position of the phenyl ring in claim 1 and the claim does not clearly set forth the distinction in type of substituents intended for phenyl ring. This applies to the definition of R_4 in claims 21 and 22 as well. In particular, claim 22 which is dependent on claim 21, recites that the R_4 substituent is in the meta position and therefore, encompasses all of the subsituents recited in claim 21 as

the substituents intended for the 3-position, which is broader than the substituent list provided for the 3-position in claim 1.

8. Claim 23 recites the limitation: $(R_4)_n$ as the substituent on the phenyl ring in structural formula (V), wherein n is 0, 1, or 2. There is insufficient antecedent basis for this limitation in claim 1 on which claim 23 is dependent (via claim 7). In claim 1, the formula (I) has a substituent R_2 at the analogous position which is defined to be "a phenyl radical that is substituted at least in the 3-position". However, the dependent claim 23 has a formula wherein the phenyl may not have any substituent, for example, when n is 0. This is inconsistent with the base claim on which claim 23 is dependent. Further, the scope of R_4 goes beyond the substituents intended at the 3-position of the phenyl ring in claim 1 and the claim does not clearly set forth the distinction in type of substituents intended for phenyl ring. This applies to the definition of R_4 in claims 24 and 25 as well. In particular, claim 25 which is dependent on claim 24, recites that the R_4 substituent is in the meta position and therefore, encompasses all of the subsituents recited in claim 24 as the substituents intended for the 3-position, which is broader than the substituent list provided for the 3-position in claim 1.

Duplicate Claims

Applicant is advised that should claim 5 be found allowable, claim 6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a

substantial duplicate of the allowed claim. See MPEP § 706.03(k). Since claim 5 does not contain a definition for R_2, it is understood that for claim 5, R_2 definition is as provided in claim 1. Claim 6, dependent on claim 5, repeats the definition of R_2 from claim 1 and therefore, the existence of claim 6 appears to be redundant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Deepak Rao/
Primary Examiner
Art Unit 1624

January 6, 2011